

**Notice of Allowability**

Application No.

09/491,982

Applicant(s)

SHAUGHNESSY ET AL.

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 3/21/2005.
2. ☒ The allowed claim(s) is/are 1, 3, 14, 43-50, renumbered, 1, 2, 3, 4-11, respectively.
3. ☒ The drawings filed on 04 February 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 09/314,152.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

*Prema Mertz*  
**PREMA MERTZ**  
**PRIMARY EXAMINER**

RD

Art Unit: 1646

1. Claims 1, 3, 14, 43-50 are allowable and have been renumbered 1, 2, 3, 4-11, respectively.
2. The declaration by Stephen Shaughnessy under 37 CFR § 1.132 submitted on 3/21/2005 is persuasive and sufficient to overcome the 35 USC § 103(a) rejections of claims 1, 3, 14, 43-49 as being unpatentable over Girasole et al. in view of Kishimoto et al. (U.S. Pat. No. 5,888,5100) and claim 50 as being unpatentable over Girasole et al (1995) in view of Kishimoto et al. (US Patent No. 5,888,510) as applied to claims 1, 3, 14, 43-49 above, and further in view of Queen et al. (US Patent No. 5,530,101) because of the showing in the declaration that the activities of osteoclast and osteoblast though complementary are not balanced in the sense of a see-saw where, when one goes up, the other goes down. For example, the references by Wronski et al (1985, 1986, 1988) provided in the declaration demonstrate that ovariectomization results in an increase in both resorption and bone formation. Therefore, the submitted declaration is sufficient to overcome the standing 35 USC § 103(a) rejections of claims 1, 3, 14, 43-50.
3. The following is an Examiner's Statement of Reasons for Allowance:

None of the prior art of record describe or suggest a method for the treatment of a clinical condition comprising increased bone resorption or decreased bone formation, the method comprising administering to said patient an effective amount of an anti-IL-11 antibody, which inhibits the formation of a tertiary complex of Interleukin-11 (IL-11), Interleukin-11 receptor (IL-11R), and glycoprotein 130 (gp130), to increase osteoblast-mediated bone formation and to decrease osteoclast-mediated bone resorption.

Art Unit: 1646

4. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
April 14, 2005